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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BROWN, MICHAEL A

ART UNIT	PAPER NUMBER
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3764

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DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749254

Applicant(s)

S. Kouac et al

Examiner

Michael Brown

Group Art Unit

3764

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-39 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-39 is/are rejected.
- ☒ Claim(s) 8 and 16-39 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
 - ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference numbers 30 and 32 are missing from the drawings. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not clear how the adhesive extends below the finger cot. It is not clear as what the barrier, the barrier layer or the membrane are in reference to. The specification does not recite any support for these structural limitations.

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4. Claims 1-26 and 28-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear as to what the barrier layer is in reference to. In claim 16, it is not clear as to what the physical barrier is in reference to. In claim 28, it is not clear as to what the barrier is in reference to. In claim 30, it is not clear as to what the membrane is in reference to. In claim 34, it is not clear as to what the barrier is in reference to.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fenwick.

Fenwick discloses in figures 1-11 a medical device comprising a sheet 10, of flexible material having an aperture 13, an adhesive backing 38, a finger cot 14 and a barrier layer (the sheath portion of the finger cot).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenwick in view of Thomalla.

Fenwick discloses in figures 1-11 a medical device, substantially as claimed. However, Fenwick does not disclose adhesive tabs disposed on the sheet or located proximate the lower corners of the sheet. Thomalla teaches in figure 1 a medical device comprising a sheet 12 having adhesive tabs (34, 36) located on the sheet and adhesive tabs 38 located proximate (fig. 1), the lower corner of the sheet. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the adhesive tabs as taught by Thomalla could be incorporated into the sheet of the medical device as disclosed by Fenwick in order to be able to secure the sheet to the chest, sides of the torso and legs of the patient.

9. Claims 2-3, 5, 9-10, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenwick in view of Taylor.

Fenwick discloses in figures 1-11 a medical device substantially as claimed, further comprising what appears to be a pouch portion (in fig. 1, the lower section 31 is shaped as a pouch) and a drain port 22. However, Fenwick does not recite that the funnel section 31 is a

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pouch or a stiffener in the funnel. Taylor teaches in figure 6 a medical device comprising a pouch 110 and a stiffener 118. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the pouch and the stiffener located in the pouch as taught by Taylor could be substituted for the funnel shape as disclosed by Fenwick because the two devices are interchangeable. Either device could be used to funnel body fluids into a drain port. The stiffener would be used to retain the open end of the pouch open during use. It is inherent that the aperture size could be between two and six inches in diameter or four inches in diameter because the dimensions of the aperture are not critical.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 2 above, and further in view of Neal.

Neal teaches in figure 1-2 a medical device comprising a pouch 30 having graduated markings (fig. 2) on the pouch. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the graduate markings on a pouch as taught by Neal could be incorporated into the pouch of the medical device as disclosed by Fenwick and taught by Taylor in order to be able to gauge the amount of fluid that flows into the pouch.

11. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenwick in view of Baker.

Fenwick discloses in figures 1-11 a medical device, substantially as claimed. However, Fenwick does not disclose an antimicrobial agent disposed on the sheet or in the adhesive. Baker teaches in figures 1-11 a medical device comprising a sheet 12 and an adhesive 14 that includes

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antimicrobial agent (col. 6, lines 24-27). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the medical device as disclosed by Fenwick could be fabricated with an antimicrobial agent on the sheet and in the adhesive as taught by Baker in order to use the antimicrobial agent to treat any cuts or injuries that the patient might incur while the sheet is attached to the patient during a medial procedure.

12. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenwick in view of Neal.

Fenwick discloses in figures 1-11 a medical device, substantially as claimed. However, Fenwick does not disclose the aperture being oval shaped. Neal teaches in figures 1-2 a medical device comprising an aperture 24 that is oval shaped. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the aperture as disclosed by Fenwick could be oval shaped as taught by Neal to have an aperture of sufficient size to provide access to the crotch area of the patient. It is inherent that the aperture could be four inches long.

Allowable Subject Matter

13. Claims 16, 27-28 and 34 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

14. Claims 8, 17-26, 29-33 and 35-39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

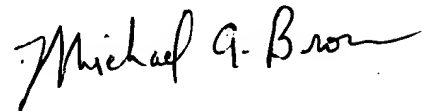
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Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jessamine and Cawood, each discloses a medical device with a finger cot. Although both of these references discloses structural limitations recited in the claims, neither was used to reject any claims, in the first office action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is (703) 308-2682.

M. Brown
May 22, 2003

A handwritten signature in black ink that reads "Michael A. Brown". The signature is written in a cursive, flowing style.

Michael A. Brown
Primary Examiner